

## **REMARKS**

Claims 1-36 as amended are pending in the present application. In the Office Action Summary, the Examiner stated in the Disposition of Claims that Claims 2-9, 17, 18 and 34 are withdrawn from consideration. Applicants submit that Claim 34 is a generic claim and therefore should not be withdrawn. Instead, Claim 35 which belongs to unelected Species I should be withdrawn from consideration. Furthermore, claims 1, 11, 13, 14, 19, 28-31, 33 and 36 have been amended. More specifically, claims 1, 11, 13, 19 and 36 have been amended to clarify that the expandable assembly is connected to the distal end of the elongated member. Support for this amendment may be found in the published specification, *inter alia*, at paragraphs [0029] and [0040]. In addition, claims 11, 13 and 19 have been rewritten in independent form to include all recitations of the base claim and any intervening claims. Also, claim 14 has been amended to correct a typographical error by including the phrase "at a point more distal". Support for such amendment to claim 14 can be found at, *inter alia*, paragraph [0040] of the published specification. Lastly, claims 28-31 and 33 have been amended to clarify that the biologically active materials of claims 28-31 and the adhesive material of claim 33 comprise at least one of the recited biologically active material or adhesive material. No new matter has been added by these amendments.

Reconsideration and allowance of the present application in view of the remarks below are respectfully requested.

### **I. INFORMATION DISCLOSURE STATEMENT**

A Second Information Disclosure Statement and List of References Cited by Applicant was filed September 9, 2003, a courtesy copy of which is enclosed herewith as Exhibit A. In the Office Action dated October 23, 2003, the Examiner did not initial the references on the List of References Cited by Applicant that was filed September 9, 2003. Therefore, Applicants respectfully request that these references be considered and entered into the file of the present application.

### **II. DRAWING OBJECTIONS**

The Examiner has objected to the drawings on the ground that the drawings "fail to show a plunger in elected species II as described in the specification." It is respectfully

submitted that while a plunger is shown in the non-elected species I, Figures 1a, 1b, 1c, 1d, 1e, and 1f, a plunger is not an essential structural detail for elected species II, Figures 4a and 4b. A plunger may be present in one embodiment of species II as indicated in the specification on page 3 line 37 to page 4 line 4 but not in another embodiment as indicated in the specification on page 4 lines 5 to 22. It is respectfully requested that the Examiner's objection to the drawings be withdrawn.

### **III. CLAIM REJECTION UNDER 35 U.S.C. § 112**

The Examiner has rejected claim 30 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has objected to the phrase "the genetic materials" in claim 30 as lacking antecedent basis. Applicants disagree with this rejection. Claim 30 is dependent on claim 28. Claim 28 as amended recites that the biologically active material comprises at least one of cells, genetic materials and drugs. Accordingly, the term "genetic materials" in claim 30 has antecedent basis. Therefore, withdrawal of this rejection is respectfully requested.

### **IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 103**

The Examiner has rejected claims 1, 10, 15, 20-33 and 36 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,693,085 to Buirge *et al.* ("Buirge"). Applicants respectfully submit that Buirge *et al.* does not render the present invention obvious. As detailed below, the cited reference neither describes nor suggests the presently claimed subject matter.

The present invention relates to a medical device for delivery of a patch to body tissue for the administration of a biologically active material. The device comprises an elongated member having a distal end and an expandable assembly disposed at and connected to the distal end of the elongated member. The patch has two opposing surfaces, one of the opposing surface comprises an adhesive material and a biologically active material. The other opposing surface is disposed upon the expandable assembly.

Buirge teaches a vascular prostheses comprising a stent **10** and a covering sleeve **12** which comprises collagen material. Unlike the present invention, Buirge does not disclose a

medical device comprising an elongated member with an expandable assembly disposed at and connected to the distal end of the elongated member. In fact, Buirge teaches away from the present invention by disclosing that its stent **10**, which the Examiner alleges is an expandable assembly, is separated from the catheter, which the Examiner alleges is the elongated member of the present invention used to implant the stent. By teaching that the stent **10** of Buirge is separated from the catheter used to implant the stent, Buirge teaches that its catheter is not connected to its stent. Thus, Buirge teaches away from an elongated member being connected to the expandable assembly as recited in the present invention.

Also, Buirge does not disclose or suggest a patch having two opposing surfaces in which one of the opposing surfaces comprises an adhesive material and a biologically active material and the other opposing surface is disposed upon at least one wire element of the expandable assembly. Assuming, for the sake of argument, that the sleeve **12** of Buirge is a patch, which in Applicants opinion it is not, Buirge does not teach or suggest that an adhesive is placed on the side of the sleeve that is opposite the side of the sleeve that contacts the stent **10**. In fact, by disclosing that the sleeve is heat bonded to the stent on the side of the sleeve that contacts the stent, Buirge suggests that adhesive is placed on the side of the sleeve that contacts the stent, not the opposing side (col. 11, lines 53-65). Thus, Buirge teaches away from the invention where the adhesive is placed on the side of the patch opposite the side of the patch that contacts the expandable assembly. Therefore, Buirge does not teach or suggest the present invention. Applicants respectfully submit that rejections of Claims 1, 10, 15, 20-33 and 36 under 35 U.S.C. § 103(a) should be withdrawn.

#### **V. ALLOWABLE SUBJECT MATTER**

The Examiner stated that Claims 11-14, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 11, 13, and 19 have been amended to include all of the limitations of the base claim and intervening claim. Claims 12 and 14 depend on claims 11 and 13, respectively. As such, allowance of Claims 11-14, and 19 are respectfully requested.

**VI. CONCLUSION**

Applicants submit that the pending claims satisfy all of the criteria for patentability and are in condition for allowance. If the Examiner has any questions, please telephone the undersigned. Please charge any required fee to Deposit Account 503013.

Respectfully submitted,

Date: March 24, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Naimark et al. Confirmation No.: 3968  
Serial No.: 09/977,758 Art Unit: 3763  
Filed: October 15, 2001 Examiner: Kevin C. Sirmons  
For: MEDICAL DEVICE FOR Attorney Docket No.: 10177-030-999  
DELIVERING PATCHES

SECOND INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of:

☒ Each U.S. patent application publication and U.S. and foreign patent;

☐ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;

☐ all other information or portion which caused it to be listed on the PTO-1449.

1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.

1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):

☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);

☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ In accordance with 37 C.F.R. §1.97(e)(2), it is certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known by any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

*(Check appropriate Items 6a, 6b and/or 6c)*

- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.
7. ☒ This is a Second Information Disclosure Statement. (Check Item 7a)
- 7a. ☒ This Second Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on November 2, 2001. The references contained in this Second Information Disclosure Statement were first cited in the International Search Report dated August 29, 2003, in a counterpart PCT international application PCT/US02/33404. A copy of this International Search Report is listed as BJ in the attached revised form PTO-1449.
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- ( Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Pennie & Edmonds LLP Deposit Account No. 16-1150.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

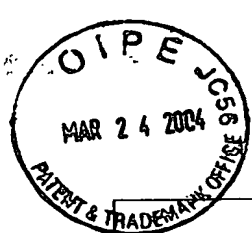
Respectfully submitted,

Date: September 9, 2003

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<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)	ATTY. DOCKET NO.	APPLICATION NO.
	10177-030-999	09/977,758
	APPLICANT Naimark et al.	
	FILING DATE	GROUP
	October 15, 2001	3763

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BI	5,829,447	Nov. 3, 1998	Stevens, et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	BJ	International Search Report of PCT/US02/33404

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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